

REMARKS

In view of the foregoing amendment and the following remarks, Applicants respectfully request reexamination of the present application. Claim 1 has been amended.

Rejections – 35 USC §102

The Examiner has rejected Claims 31, 40, 41, 44, and 47 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,620,351 by Gupta et al. The Examiner has also maintained the rejection of Claims 1-5, 7-22, 31, 32, 34-42, 44, 46, 64-67, 69-84, 93-95, and 97-112 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,985,356 by Schultz et al. Applicants respectfully traverse these rejections.

The Examiner asserts that Gupta et al. anticipates Claims 31, 40, 41, 44, and 47, because Gupta et al. discloses making particles of a desired substance by applying a dispersion including at least two or more materials which react on a surface to form the desired substance. The Examiner further states that Gupta et al. disclose that a reactor condition (e.g., vibration of the surface) can be varied to produce a differential condition in the final products, such as a difference in size or agglomeration of the particles.

The Examiner asserts that Claims 1-5, 7-22, 31, 32, 34-42, 44, 46, 64-67, 69-84, 93-95, and 97-112 are anticipated by Schultz et al. The Examiner asserts that Schultz et al. disclose a process which includes depositing a plurality of reactive materials upon specific regions of a substrate and analyzing various properties of the deposited materials. The materials may be a plurality of materials of different compositions.

Relevant Legal Doctrines – 35 USC §102

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Applicants submit that the Examiner has not met the burden required under 35 U.S.C. §102 with respect to Gupta et al. and Schultz et al.

U.S. Patent No. 6,620,351 by Gupta et al.

Gupta et al. disclose a process for producing nanoparticles or microparticles using supercritical fluids. The process disclosed by Gupta et al. involves filling a vessel with an antisolvent fluid that is near or above its critical pressure, and near or above its critical temperature. Col. 9 lines, 53-57. A horn surface is vibrated at a desired amplitude. Col. 9, lines 61-63. Then a dispersion containing one or more desired substances in a solvent is sprayed so that it contacts the vibrating horn surface. Col. 10, lines 3-12. As soon as the dispersion contacts the vibrating surface, it is atomized into droplets that form particles due to the rapid removal of the solvent from the droplets by the supercritical antisolvent. Col. 10, lines 11-14. Gupta et al. disclose that the size of the particles and agglomeration of the particles can be controlled by changing the vibration intensity of the vibrating horn surface. Col. 5, lines 60-65 and Col. 6, lines 10-15. One advantage of the process disclosed by Gupta et al. is the ability to generate particles with narrow size distribution. Col. 6, lines 31-34.

U.S. Patent No. 5,985,356 by Schultz et al.

Schultz et al. is directed to a method and apparatus for the preparation and use of a substrate having an array of diverse materials in predefined regions on the substrate. The substrate is prepared by delivering components (i.e., reactants) of materials to predefined regions on the substrate and simultaneously reacting the components to form at least two materials. See, e.g., the Abstract. An array of materials having different chemical compositions is formed by delivering the different reactants to pre-defined regions on the substrate in a step-wise fashion. Multiple deposition steps and masking techniques are used to vary the concentration of a particular reactant that is deposited on a given region of the substrate. A small, precisely metered amount of each reactant component is delivered into each reaction region. (Col. 10, lines 37-39 and Col. 15, lines 8-17). By varying the amount of the individual reactants deposited from one region to another region, different materials can be formed on the substrate.

The Terms “Real-Time Basis” and “Continuous”

With respect to Applicants' prior arguments, the Examiner states at page 7 of the Office Action that:

With regard to varying a process “continuously” or in “real time”, it is unclear what the specific definition of such terms would be. For example, a process which occurs over a total time of 100 seconds could be seen as a ten step process each step 10 seconds long, a 100 step process each 1 second long, or a 100,000 step process each 1 millisecond long. Clearly, in either the prior art or the claimed invention, if one is forming a material of composition A at one location and a material of composition B at another location, some difference in time occurs between these two forming steps. No clear definition is set forth in the present specification as to how long or short any steps in the inventive process may be that still fall within the scope of the continuous or real time variance in the process.

Although the Examiner has not formally rejected the claims under 35 USC § 112, this statement by the Examiner will be treated as such. The essential inquiry pertaining to the requirement that a claim be definite under 35 USC 112 is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of:

- (A) The content of the particular application disclosure;
- (B) The teachings of the prior art; and
- (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

In reviewing a claim for compliance with 35 U.S.C. 112, second paragraph, the Examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. 112, second paragraph, by providing clear warning to others as to what constitutes infringement of the patent. See, e.g., *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1379, 55 USPQ2d 1279, 1283 (Fed. Cir. 2000). The test for definiteness under

35 U.S.C. 112, second paragraph, is whether “those skilled in the art would understand what is claimed when the claim is read in light of the specification.” *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986).

Page 6, lines 15-16 of the present specification defines the term “real-time basis” as meaning that “the variable, such as precursor composition, is changed without any substantial interruptions in the operation of the reactor system.”

The term “continuously” has its ordinary and accustomed meaning. *Tate Access Floors, Inc. v. Maxcess Technologies, Inc.*, 222 F.3d 958, 965, 55 USPQ2d 1513, 1517 (Fed. Cir. 2000) (‘terms in a claim are to be given their ordinary and accustomed meaning.’). Attached in Appendix A is a copy of page 301 of the American Heritage College Dictionary, defining the term continuous as: “uninterrupted in time, sequence, substance or extent.” *Inverness Medical Switzerland GmbH v. Princeton Biomeditech Corp.*, 309 F.3d 1365, 1369, 64 USPQ2d 1926 (Fed. Cir. 2002) (“It is well settled that dictionaries provide evidence of a claim term’s ‘ordinary meaning.’”).

It is respectfully submitted that when the claims of the present application are read in light of the application disclosure, the teachings of the prior art and the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art, that the claim satisfy the requirements of 35 U.S.C. § 112. Specifically, the application disclosure makes it abundantly clear what the Applicant’s mean by the term continuously and the term real-time. Further, one possessing ordinary skill in the art would readily understand what is meant by these terms.

§ 102 Rejections Based on Gupta et al.

Both independent Claims 31 and 44 require that a reactor condition be varied on a real-time basis such that the reacted precursor particles comprise first reacted precursor particles at a first time and second reacted precursor particles at a second time. Gupta et al. do not disclose that a condition of a reactor is varied on a real time basis without any substantial interruption of the reactor system. Gupta et al. disclose that the vibration amplitudes of the vibrating surface affect particle size, and therefore can be changed to change particle size, but not that it can or should be changed on a real-time basis.

Moreover, the disclosure of Gupta et al. is inconsistent with the Examiner's interpretation. None of the examples disclosed by Gupta et al. are produced by varying the vibration amplitude on a real-time basis. Indeed, the data shown in the figures (Figures 4-25) clearly illustrate that every experiment or batch of particles disclosed by Gupta et al. is produced by keeping the vibration amplitude constant at one particular value – by maintaining a constant power to the vibration source to produce a powder of narrow size distribution.

Because the vibration controls the particle size, varying the amplitude of the vibrating surface on a real-time basis as the Examiner claims is disclosed by Gupta et al. would produce particles of varying size (i.e., large size distribution). This is in direct contrast to the teachings of Gupta et al., which state at Col. 6, lines 33-34 that “[o]ne of the main requirements of such small particles in several applications is a narrow particle size distribution.” Thus, not only do Gupta et al. fail to disclose varying a reactor condition on a real-time basis, but the condition that the Examiner asserts that Gupta et al. can vary on a real-time basis, namely vibration of the surface, would produce particles that are inconsistent with the teachings of Gupta et al. Therefore, it is respectfully submitted that independent Claims 31 and 44 are not anticipated by Gupta et al.

Claims 40 and 41 are also allowable based on their dependency on Claim 31, and Claim 47 is allowable based on its dependency on Claim 41. Additionally, the dependent claims recite limitations that further distinguish them over Gupta et al. Specifically, with respect to Claim 40, Gupta et al. do not disclose collecting the particles on a substrate and analyzing the reacted precursor particles on the substrate. Gupta et al. do not disclose that a first reacted precursor portion is collected at a first predetermined location on a substrate and that a second reacted precursor portion is collected at a second predetermined location on a substrate, as recited in Claim 41. Consequently, Claims 40, 41 and 47 are also allowable over Gupta et al.

§ 102 Rejections Based on Schultz et al.

Schultz et al. do not disclose or suggest varying the precursor composition on a real-time basis as is required by independent Claim 1. Schultz et al. disclose that different materials can be formed by depositing reactants at different locations on a substrate and

then reacting the reactants on the substrate. The reactants are deposited *sequentially*, requiring *discrete* multiple steps to form different material compositions and possibly intermediate masking steps.

Further, Claim 1 has been amended to recite that the particles are formed in a dispersed state. Schultz et al. does not disclose the fabrication of particles in a dispersed state.

In view of the foregoing, it is respectfully submitted that Claim 1 is not anticipated by Schultz et al. Claims 2-5 and 7-22 depend upon Claim 1 and include all the limitations thereof. These claims also further define the invention over Schultz et al. For example, dependent Claims 10-12 recited different types of reactors, which would not be useful in the method disclosed by Schultz et al.

As stated above, independent Claim 31 recites a process for the fabrication and analysis of particulate materials, including the steps of providing a precursor composition and continuously reacting the precursor composition in a reactor to form reacted particles, wherein a reactor condition is varied in a controlled manner to form at least two portions of the reacted precursor particles. The portions of reacted precursor particles are then analyzed for at least one material property.

Schultz et al. do not disclose or suggest continuously reacting a precursor composition and varying a reactor condition in a controlled manner and on a real time basis to form different reacted precursor particles. Applicants respectfully submit that Claim 31 is not anticipated by Schultz et al. Claims 32 and 34-42 depend upon Claim 31, include all of the limitations thereof and are allowable for the same reasons as Claim 31.

Independent Claim 44 recites a method for selecting a particulate material having a desired property, including the steps of reacting dispersed precursor droplets in a reactor to form reacted precursor particles and measuring at least one material property of the particles while dispersed in a carrier gas.

Schultz et al. do not disclose or suggest continuously providing a precursor composition to a reactor in the form of precursor droplets. Schultz et al. merely disclose that reactant solutions can be deposited sequentially onto a substrate. Only then is the substrate provided to a reactor or otherwise reacted to form the material. Claim 44 also recites the step measuring at least one material property of the precursor particles *while*

they are dispersed in the carrier gas. Clearly, Schultz et al. do not disclose or suggest dispersing reactive precursor particles in a carrier gas and measuring the particle properties in that state.

In view of the foregoing, Applicants respectfully submit that Claim 44 is not anticipated by Schultz et al. Claim 46 depends upon Claim 44 and includes all of the limitations thereof and is allowable for the same reasons as Claim 44.

Independent Claim 64 recites a method for the fabrication of a plurality of particulate materials by continuously providing a precursor composition to a reactor, continuously reacting the precursor composition in the reactor under at least one reactor condition to form reacted precursor particles and collecting the reacted precursor particles. The precursor composition is varied in a controlled manner and on a real-time basis such that the reacted precursor particles include a first reacted precursor portion at a first time and a second reacted precursor portion at a second time and at least one material property of the first reacted precursor portion is different than the one material property of the second reacted precursor portion, and where the precursor composition is varied on a real time basis and the first reacted precursor portion has a different chemical composition than the second reacted precursor portion.

Schultz et al. do not disclose or suggest continuously providing a precursor composition to a reactor and continuously reacting a precursor composition in the reactor. Also, Schultz et al. do not disclose or suggest varying the precursor composition on a real-time basis. Rather, the different materials are formed by sequential deposition and/or masking steps. For the foregoing reasons, it is respectfully submitted that Claim 64 is not anticipated by Schultz et al. Claims 65-67 and 69-84 depend upon Claim 64 and include all of the limitations thereof and are allowable for the same reasons as Claim 64.

Independent Claim 93 recites a method for the fabrication of a plurality of particulate materials, including the steps of continuously providing a precursor composition having at least a first precursor component and a second precursor component to a reactor, continuously reacting the precursor composition in the reactor under at least one reactor condition to form reacted precursor particles, and collecting the reacted precursor particles, wherein the concentration of at least one of the first and second precursor components in the precursor composition is varied in a controlled manner and on a real-time basis such

that the reacted precursor particles include a first reacted precursor portion at a first time and a second reacted precursor portion at a second time and at least one material property of the first reacted precursor portion is different than the one material property of the second reacted precursor portion.

As previously stated, Schultz et al. do not disclose or suggest continuously providing a precursor composition to a reactor and continuously reacting the precursor composition in the reactor. Therefore, it is respectfully submitted that independent Claim 93 is not anticipated by Schultz et al. Claims 94, 95 and 97-112 depend upon Claim 93 and include all of the limitations thereof and are allowable for the same reasons as Claim 93. Additionally, dependent Claims 100-102 recited different types of reactors, not disclosed or suggested by Schultz et al.

Rejections – 35 USC § 103

The Examiner has rejected Claims 43, 45 and 46 under 35 U.S.C. 103(a) as being unpatentable over Gupta et al.. The Examiner has also maintained the previous rejection of Claims 6, 23-30, 33, 43, 45, 47-63, 68, 85-92, 96 and 113-120 under 35 U.S.C. 103(a) as being unpatentable over Schultz et al. Applicants respectfully traverse these rejections.

Relevant Legal Doctrine – 35 USC §103

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). In addition, there must be a teaching or suggestion to make the claimed combination and a reasonable expectation of success that are found in the prior art, and not in the applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). In determining the propriety of the Patent Office case for obviousness in the first instance, it is necessary to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the reference before him to make the proposed substitution, combination, or other modification. *In re Linter*, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972).

§ 103 Rejections Based on Gupta et al.

With respect to Claim 43, the Examiner states that one skilled in the art would want to measure properties as soon as possible in order to minimize the production of material with unwanted properties. Claim 43 is dependant on Claim 31 and is patentable over Gupta et al. based on all the reasons stated above with respect to Claim 31. Even assuming that a person of ordinary skill in the art would want to minimize the production of material with unwanted properties, the Examiner has provided no line of reasoning as to why the limitation recited in Claim 43 would achieve the desired goal of minimizing the production of material with unwanted properties. At most, the Examiner has provided a reason for making only a small batch of material, or limiting the amount of precursor provided to a reactor, and not a motivation for analyzing particles as they leave a reactor.

Claims 45 and 46 are dependent on Claim 44 and are patentable over Gupta et al. based on all the reasons stated above with respect to Claim 44. Additionally, with respect to Claim 45 there is no suggestion in Gupta et al. that the aerodynamic diameter is a useful property to measure in the particles. As stated in the specification at page 17, the aerodynamic diameter is important for pharmaceuticals that are to be used in inhalation devices "to ensure the accurate delivery of a prescribed amount of the pharmaceutical." Gupta et al. do not teach or suggest that the pharmaceutical particles produced by the process they disclose can be used in inhalation devices. Thus, there is no motivation or suggestion in Gupta et al. that measuring the aerodynamic diameter would be useful, making Claim 45 further patentable.

§ 103 Rejections Based on Schultz et al.

Claims 6 and 23-30 depend upon Claim 1, discussed above, and are patentable over Schultz et al. for all the reasons stated above with respect to Claim 1. Claims 33 and 43 depend upon Claim 31, discussed above, and are patentable over Schultz et al. for all the reasons stated above with respect to Claim 31. Claims 45 and 47 depend upon Claim 44, discussed above and are patentable over Schultz et al. for all the reasons stated above with respect to Claim 44.

Independent Claim 48 recites a method for the continuous fabrication of a plurality of particulate electrocatalyst compositions by providing a precursor to the electrocatalyst

having at least first and second precursor components, reacting the precursor to form a particulate reacted precursor and collecting the particulate reacted precursor, where the precursor composition is controllably changed during the fabrication method. The precursor composition of Schultz et al. (reactants) is not changed during the fabrication method - in Schultz et al. the same precursor composition is deposited numerous times to attain a material having a different composition. Nor do Schultz et al. suggest that the precursor composition is or should be controllably changed during the fabrication method. In view of the foregoing, it is respectfully submitted that Claim 48 is not obvious in view of Schultz et al. Claims 49-60 depend upon Claim 48 and include all of the limitations thereof and are allowable for the same reasons as Claim 48.

Independent Claim 61 recites a method for the continuous fabrication of a plurality of pharmaceutical powders. The method includes the steps of providing a precursor to a pharmaceutical composition including first and second precursor components, generating precursor droplets from the precursor and reacting the precursor to form pharmaceutical particles, wherein the pharmaceutical composition is controllably changed during the fabrication method.

Schultz et al. do not disclose or suggest fabricating pharmaceutical powders. Further, Schultz et al. do not disclose or suggest changing the composition of a pharmaceutical during the fabrication method. In view of the foregoing, it is respectfully submitted that Claim 61 is not obvious in view of Schultz et al. Claims 62, 63, 68 and 85-92 depend upon Claim 61, include all of the limitations thereof and are patentable based on all the reasons discussed with respect to Claim 61.

Claims 96 and 113-120 depend upon Claim 93, include all of the limitations thereof and are patentable based on all the reasons discussed above with respect to Claim 93.

Provisional Double Patenting Rejection


The Examiner has provisionally rejected Claims 1-5, 13-15, 18-21, 24-27, 31, 40-43, 64-67, 75-77, 80-83, 86-89, 93-95, 103-105, 108-111, and 114-117 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-85 of U.S. Patent Application Serial No. 09/821,848.

The rejection under double patenting is acknowledged, and a terminal disclaimer will be filed in this case as soon as claims in U.S. Patent Application Serial No. 09/821,848 are otherwise allowable.

Applicants believe that all pending claims are in condition for allowance and such disposition is respectfully requested. In the event that a telephone conversation would further prosecute and or expedite allowance, the Examiner is invited to contact the undersigned.

Respectfully submitted,

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